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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/729,264	11/28/00	WELCHER	A	A-692

021069
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HM12/0504

EXAMINER	
WHITEMAN, B	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 05/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/729,264	WELCHER ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Claims 1-56 are pending and under consideration in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 10, 11, 46-48, and 55, drawn to an isolated nucleic acid molecule comprising a nucleotide sequence selected from: the nucleotide sequence as set forth in SEQ ID NOs: 1, 3, 5, 7, 9, 11, or 13; nucleotide sequences encoding the polypeptides 2, 4, 6, 8, 10, 12, 14, or 15; a vector comprising the nucleic acid of claims 1, 2, or 3; a host cell comprising the vector of claim 4; a process of producing B7-like polypeptide comprising culturing the host cell of claim 5; the process of claim 8, wherein the nucleic acid molecule comprises promoter DNA other than the promoter DNA for the native B7-like polypeptide; the isolated nucleic acid molecule according to claim 2 wherein the percent identity is determined using a computer program; a composition comprising a nucleic acid molecule of claims 1, 2, or 3 and a pharmaceutically acceptable formulation agent; a viral vector comprising claims 1, 2 or 3; a method of modulating levels of a polypeptide in an animal comprising administering to the animal the nucleic acid of claims 1, 2, or 3, classifiable in class 536, subclass 23.1, class 514, subclass 44.

II. Claims 9, 13-17, 40-45, 49-51 and 54, drawn to an isolated polypeptide comprising an amino acid sequence set forth in SEQ ID NOs: 2, 4, 6, or 8; an isolated polypeptide comprising an amino acid sequence selected from: an amino acid sequence comprising the mature form of the polypeptide of SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, and optionally further comprising an amino-terminal methionine; an isolated polypeptide encoded by a nucleic acid molecule of claims 1, 2 or 3; a polypeptide produced by the process of claim 8 ; the isolated polypeptide

according to claim 14 where in the percent identity is determined using a computer program, a composition comprising the polypeptide of claims 13, 14, or 15, and a pharmaceutically acceptable formulation agent; a polypeptide of claim 43 which is covalently modified with a water-soluble polymer; a fusion polypeptide comprising the polypeptide of claims 13, 14, or 15 fused to a heterologous amino acid sequence; a method for treating, preventing, or ameliorating a medical condition comprising administering to a patient the polypeptide of claims 13, 14 or 15 or the polypeptides encoded by the nucleic acid of claims 1, 2, or 3; a method of identifying a compound which binds to a polypeptide, classifiable in class 530, subclass 350+, class 514, subclass 12.

III. Claims 18-20 and 22, drawn to an antibody produced by immunizing an animal with a peptide comprising an amino acid sequence of SEQ ID NOs: 2, 4, 6, 8, 10, 12, or 14; an antibody or fragment thereof that specifically binds at least one polypeptide of claims 13, 14 or 15, the antibody of claim 19 that is a monoclonal antibody; a method of detecting or quantitating the amount of B7-like polypeptide using the anti-B7-like antibody of fragment of claims 18, 19, or 20, classifiable in class 800, subclass 6, class 530, subclass 387.9, class 435, subclass 4.

IV. Claims 21 and 39, drawn to a hybridoma that produces a monoclonal antibody that binds to at least one peptide comprising an amino acid sequence selected from SEQ ID NOs: 2, 4, 6, 8, 10, 12, or 14, a hybridoma that produces a selective binding agent capable of binding a polypeptide according to claim 1, 2, or 3, classifiable in class 435, subclass 331.

V. Claims 23-38, drawn to a selective binding agent or fragment thereof that specifically binds at least one polypeptide comprising amino acid sequence selected from the amino acid sequence set forth in SEQ ID NOs; 2, 4, 6, 8, 10, 12, 14; a selective binding agent or fragment

thereof comprising at least one complementarily determining region with specifically for at least one polypeptide comprising an amino acid sequence selected from SEQ ID NOs; 2, 4, 6, 8, 10, 12, or 14, a method for treating, preventing, or ameliorating a disease, condition, or disorder comprising administering to a patient an effective amount of a selective binding agent of claim 23, a selective binding agent produced by immunizing an animal with a polypeptide comprising an amino acid sequence selected SEQ ID NOs: 2, 4, 6, 8, 10, 12, or 14, classifiable in class 530, subclass 387.9, class 514, subclass 2, class 800, subclass 6.

VI. Claims 12 and 52, drawn to a method of diagnosing a pathological condition or a susceptibility to a pathological condition in a subject comprising; (a) determining the presence or amount of expression of the polypeptide of claims 13, 14, or 15 or the polypeptide encoded by the nucleic acid molecule of claims 1, 2, or 3 in a sample; and (b) diagnosing a pathological condition or a susceptibility to a pathological condition based on the presence or amount of expression of the polypeptide, a process for determining whether a compound inhibits B7-like polypeptide activity or production comprising exposing a cell according to claim 5, 6, or 7 to the compound, and measuring B7-like polypeptide activity or production in said cell, classifiable in class 530, subclass 350+, class 514, subclass 2.

VII. Claim 53, drawn to a device, comprising; (a) a membrane suitable for implantation; and (b) cells encapsulated within said membrane, wherein said cells secrete a protein of claims 13, 14, 15, and wherein said membrane is permeable to said protein and impermeable to materials detrimental to said cells, classifiable in class 514, subclass 2.

VIII. Claim 56, drawn to a transgenic non-human mammal comprising the nucleic acid molecule of claims 1, 2, or 3, classifiable in class 800, subclass 8.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II, III, IV, V, VII, VIII are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are distinct due to invention I encompassing a DNA sequence encoding at least one sequence (SEQ ID NOs: 1-14) of a B7-like gene product; Invention II encompasses at least one isolated polypeptide comprising at least one sequence from SEQ ID NOs 1-14; Invention III encompasses antibodies comprising at least one amino acid sequence from SEQ ID NOs: 2, 4, 6, 8, 10, 12, or 14; Invention IV encompasses a hybridoma that binds at least one peptide comprising of at least one amino acid sequence from SEQ ID NOs: 2, 4, 6, 8, 10, 12, or 14; Invention V encompasses a selective binding agent that specifically binds at least one polypeptide comprising an amino acid sequence selected from SEQ ID NOs 2, 4, 6, 8, 10, 12, or 14; Invention VII encompasses a device comprising; (a) a membrane suitable for implantation; and (b) cells encapsulated within said membrane, wherein said cells secrete a protein of claims 13, 14, 15, and wherein said membrane is permeable to said protein and impermeable to materials detrimental to said cells; Invention VIII encompasses a transgenic non-human mammal comprising the nucleic acid of claims 1, 2 or 3. Though each product is related in some way to the nucleic acid of group I. Each product is distinct, does not require the other to be made and used and is separately patentable.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because each of the methods of inventions I, II, III, V, and VI constitutes patentably

distinct inventions for the following reasons: Each of the inventions is directed to different goals and comprises materially distinct steps, wherein each of the compositions in each invention is structurally distinct and/or generates distinct mechanisms and functional effects as indicated above. The scope of each of the cited inventions encompasses an employed method, which generates distinct function(s) and effect(s), and furthermore does not necessarily overlap with that of another invention. Furthermore, none of the method steps cited in inventions I, II, III, V, and VI recite a similar method of using nucleic acid from invention I, proteins in inventions II, VI; antibodies in invention III, or binding agents in invention V. Each of the inventions I, II, III, V, and VI comprises materially distinct steps, and/or generates different functions and effects, and thus, is not required for use with one another. Therefore the invention of group VI is distinct from groups I-V and VII-VIII.

Invention I contains claims directed to the following patentably distinct species of the claimed invention: a nucleic acid sequence set forth in SEQ ID NOs: 1, 3, 5, 7, 9, 11, or 13; or a nucleic acid sequence encoding SEQ ID NOs: 2, 4, 6, 8, 10, 12, or 14.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Invention II contains claims directed to the following patentably distinct species of the claimed invention: an amino acid sequence set forth in SEQ ID NOs: 2, 4, 6, 8, 10, 12, or 14; or a polypeptide encoded by a nucleic acid sequence of SEQ ID NOs 1, 3, 5, 7, 9, 11, or 13.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Invention III contains claims directed to the following patentably distinct species of the claimed invention: an antibody which binds specifically to SEQ ID NOs: 2, 4, 6, 8, 10, 12, or 14.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Invention IV contains claims directed to the following patentably distinct species of the claimed invention: a hybridoma, which produces an antibody that binds to an amino acid sequence selected from SEQ ID NOs: 2, 4, 6, 8, 10, 12, or 14; or a polypeptide encoded by a nucleic acid sequence according to SEQ ID NOs: 1, 3, 5, 7, 9, 11, or 13.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Invention V contains claims directed to the following patentably distinct species of the claimed invention: a binding agent which specifically binds to SEQ ID NOs: 2, 4, 6, 8, 10, 12 or 14.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Invention VI contains claims directed to the following patentably distinct species of the claimed invention: determining the presence or amount of a polypeptide from SEQ ID NOs: 2, 4, 6, 8, 10, 12, or 14; or a polypeptide encoded by a nucleic acid molecule set forth in SEQ ID NOs: 1, 3, 5, 7, 9, 11, or 13.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Invention VII contains claims directed to the following patentably distinct species of the claimed invention: a device, wherein cells are secreting a protein set forth in SEQ ID NOs: 2, 4, 6, 8, 10, 12 or 14.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Invention VIII contains claims directed to the following patentably distinct species of the claimed invention: a transgenic non-human mammal comprising a nucleic acid molecule set forth in SEQ ID NOs: 1, 3, 5, 7, 9, 11 or 13.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory

classes of inventions, and are separately classified and searched, restriction for examination purposes as indicated is proper.

It would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims, a restriction for examination purposes as indicated s proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Tracey Johnson whose telephone number is (703) 305-2982.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on M-F, (730-400 EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached at (703) 305-4051.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner
27 April 2001

Deborah Clark

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